

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Klaus Michael Debatin et al.
Title: Smac-peptides as Therapeutics against Cancer
and Autoimmune Diseases
Appl. No.: 10/511,037
Filing Date: 01/19/2005
Examiner: Unassigned
Art Unit: Unassigned

INFORMATION DISCLOSURE STATEMENT
UNDER 37 CFR §1.56

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Submitted herewith on Form PTO/SB/08 is a listing of documents known to Applicants in order to comply with Applicants' duty of disclosure pursuant to 37 CFR §1.56.

A copy of each non-U.S. patent document and each non-patent document is being submitted to comply with the provisions of 37 CFR §1.97 and §1.98, except as noted below.

The submission of any document herewith, which is not a statutory bar, is not intended as an admission that such document constitutes prior art against the claims of the present application or that such document is considered material to patentability as defined in 37 CFR §1.56(b). Applicants do not waive any rights to take any action which would be appropriate to antedate or otherwise remove as a competent reference any document which is determined to be a *prima facie* art reference against the claims of the present application.

TIMING OF THE DISCLOSURE

The listed documents are being submitted in compliance with 37 CFR §1.97(b), before the mailing date of the first Office Action on the merits.

RELEVANCE OF EACH DOCUMENT

Documents A1- A27 were cited as being relevant during the prosecution of the corresponding International application. Copies of the documents are not being provided since copies should have been provided directly by WIPO under an exchange program between the PTO, the EPO and the JPO. A copy of the International Search Report setting forth the portion of each reference considered relevant by the examiner is attached.

The relevance of Documents A28 and A29 is explained in the specification.

Applicants respectfully request that any listed document be considered by the Examiner and be made of record in the present application and that an initialed copy of Form PTO/SB/08 be returned in accordance with MPEP §609.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 CFR §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741.

Respectfully submitted,

Date Jan 19, 2005

By Michele M. Simkin

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Substitute for form 1449B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(use as many sheets as necessary)</i>				Complete if Known		
				Application Number		10/511,037
				Filing Date		01/19/2005
				First Named Inventor		Klaus Michael Debatin
				Group Art Unit		Unassigned
				Examiner Name		Unassigned
Sheet	1	of	3	Attorney Docket Number		085449-0152

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code ² (if known)			
	A1	6,306,613	B1	BAIRD ET AL.	10/23/2001	

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Foreign Patent Document			Name of Patentee or Applicant of Cited Documents	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Office ³	Number ⁴	Kind Code ⁵ (if known)				
	A2	WO	02/16418	A	THOMAS JEFFERSON UNIVERSITY	02/28/2002		
	A3	WO	02/16402	A	BOARD OF REGENTS, THE UNIVERSITY OF TEXAS SYSTEM	02/28/2002		
	A4	WO	02/26775	A	TRUSTEES OF PRINCETON UNIVERSITY	04/04/2002		
	A5	WO	01/49719	A	UNIVERSITY OF TEXAS SYSTEM	07/12/2001		
	A6	WO	00/58488	A	INVITROGEN CORP.	10/05/2000		
	A7	WO	01/38547	A	ROSENECKER ET AL.	05/31/2001		
	A8	WO	00/29427	A	CYCLACEL LTD.	05/25/2000		
	A9	WO	99/05302	A	PERKIN ELMER CORP.	02/04/1999		
	A10	EP	0 903 408	A	BIOGEN INC.	03/24/1999		
	A11	WO	94/04686	A	BIOGEN INC.	03/03/1994		

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ⁶
	A12	ENDO ET AL., "Cysteine, basic and neutral amino acid transporter BAT1 from rat an human activated by rBAT, cDNA, and recombinant expression," DATABASE CA 'Online!, CHEMICAL ABSTRACTS SERVICE, Columbus, Ohio, US; 2001, XP002204777, retrieved from STN, Database accession no. 134:174559 HCA abstract & JP 2001 046070 A (FOUNDATION FRO SCIENTIFIC TECHNOLOGY PROMOTION, JAPAN) 20 February 2001.	
	A13	DEROSSI ET AL., "Trojan Peptides: The Penetratin System for Intracellular Delivery," TRENDS IN CELL BIOLOGY, Elsevier Science Ltd., vol. 8, February 1998, pp. 84-87, XP002940006, ISSN: 0962-924.	

Examiner Signature	Date Considered	
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¹ Unique citation designation number. ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document.

⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

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Sheet	2	of	3	Attorney Docket Number	085449-0152

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	A14	SCHWARZE ET AL., "In vivo protein transduction: delivery of a biologically active protein into the mouse," SCIENCE, American Association for the Advancement of Science, vol. 285, no. 5433, 3 September 1999, pp. 1569-1572, XP002140133, ISSN: 0036-8075.	
	A15	FISCHER ET AL., "Structure-Activity Relationship of Truncated and Substituted Analogues of the Intracellular Delivery Vector Penetratin," JOURNAL OF PEPTIDE RESEARCH, Munksgaard International Publishers, vol. 55, no. 2, February 2000, pp. 163-172, XP000899124, ISSN: 1397-002X.	
	A16	FULDA ET AL., "Release of Smac from mitochondria bypasses the Bcl-2 inhibition in type II cells and sensitizes for death receptor or drug-induced apoptosis," PROCEEDINGS OF THE AMERICAN ASSOCIATION FOR CANCER RESEARCH ANNUAL MEETING, vol. 42, March 2001, p. 552, XP002251122, ISSN: 0197-016X, abstract.	
	A17	FULDA ET AL., "Smac release from mitochondria bypasses the Bcl-2 inhibition and sensitizes tumor cells for death receptor or drug-induced apoptosis," BLOOD, November 16, 2001, vol. 98, no. 11, Part 1, pp. 572a-573a, XP002251123, ISSN: 0006-4971, abstract.	
	A18	FULDA ET AL., "Smac peptides or Smac gene transfer as a novel strategy to overcome resistance against TRAIL- or drug-induced apoptosis," PROCEEDINGS OF THE AMERICAN ASSOCIATION FOR CANCER RESEARCH ANNUAL MEETING, vol. 43, March 2002, pp. 527-528, XP002251124, ISSN: 0197-016X, abstract.	
	A19	JOHNSTONE ET AL., "Apoptosis: A link between cancer genetics and chemotherapy," CELL, vol. 108, no. 2, 25 January 2002, pp. 153-164, XP002251125, ISSN: 0092-8674.	
	A20	IGNEY ET AL., "Death and anti-death: Tumour resistance to apoptosis," NATURE REVIEWS CANCER, vol. 2, no. 4, 20 April 2002, pp. 277-288, XP002251126, ISSN: 1474-175X.	
	A21	FULDA ET AL., "Smac agonists sensitize for Apo2L/TRAIL- or anticancer drug-induced apoptosis and induce regression of malignant glioma in vivo," NATURE MEDICINE, vol. 8, no. 8, August 2002, pp. 808-815, XP002251127, ISSN: 1078-8956, abstract.	
	A22	SILKE ET AL., "The anti-apoptotic activity of XIAP is retained upon mutation of both the caspase 3- and caspase 9-interacting sites," JOURNAL OF CELL BIOLOGY, vol. 157, no. 1, 1 April 2002, pp. 115-124, XP002272040, ISSN: 0021-9525, abstract.	
	A23	EKERT ET AL., "DIABLO promotes apoptosis by removing MIHA/XIAP from processed caspase 9," JOURNAL OF CELL BIOLOGY, vol. 153, no. 3, 30 April 30, 2001, pp. 483-490, XP002272041, ISSN: 0021-9525, abstract.	
	A24	SRINIVASULA ET AL., "A conserved XIAP-interaction motif in caspase-9 and Smac/DIABLO regulates caspase activity and apoptosis," NATURE, vol. 410, 1 March 2001, pp. 112-116, XP002962286, ISSN: 0028-0836.	
	A25	VERHAGEN ET AL., "HtrA2 promotes cell death through its serine protease activity and its ability to antagonize inhibitor of apoptosis proteins," JOURNAL OF BIOLOGICAL CHEMISTRY, vol. 277, no. 1, 4 January 2002, pp. 445-454, XP002957689, ISSN: 0021-9258.	
	A26	HOLCIK ET AL., "Translation Upregulation of X-Linked Inhibitor of Apoptosis (XIAP) Increases Resistance to Radiation Induced Cell Death," ONCOGENE, vol. 19, no. 36, 24 August 2000, pp. 4174-4177, XP008007068, ISSN: 0950-9232.	

Examiner
Signature

Date
Considered

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¹ Unique citation designation number. ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document.

⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

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Sheet 3 of 3

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	A27	VERHAGEN ET AL., "Identification of DIABLO, a mammalian protein that promotes apoptosis by binding to an antagonizing IAP proteins," CELL, vol. 102, no. 1, 7 July 2000, pp. 43-53, XP002175397, ISSN: 0092-8674.	
	A28	DU ET AL., "Smac, a Mitochondrial Protein that Promotes Cytochrome c-Dependent Caspase Activation by Eliminating IAP Inhibition," CELL, vol. 102, pp. 33-42, July 7, 2000.	
	A29	CARSON ET AL., "Smac is Required for Cytochrome c-induced Apoptosis in Prostate Cancer LNCaP Cells ¹ ," CANCER RESEARCH, vol. 62, pp. 18-23, January 1, 2002.	

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